

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-----------------|----------------------|-------------------------|-------------------|--|
| 09/623,533 | 09/05/2000 | Dominique P. Bridon | REDC-1510USA | 3921 | |
| 20872 | 7590 05/16/2003 | | | | |
| MORRISON & FOERSTER LLP | | | EXAMINER | | |
| 425 MARKET STREET SAN FRANCISCO, CA 94105-2482 | | | PARKIN, JI | PARKIN, JEFFREY S | |
| | | • | ART UNIT | PAPER NUMBER | |
| | | | 1648 | 16 | |
| | | | DATE MAILED: 05/16/2003 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.





UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

DEA/FCE-1994

| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|---------------|-------------|-----------------------|---------------------|
| | | | |

| EXAMINER | | | | | |
|----------|--------------|--|--|--|--|
| ART UNIT | PAPER NUMBER | | | | |
| | | | | | |

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application

Commissioner of Patents

- 1. The communication filed on 24 February, 2003, is non-responsive to the prior Office action because the claims have been amended to include multiple independent and distinct inventions within the same claim. instance, claim 1 now recites a genus of anti-viral peptides comprising SEQ ID NOS.: 1, 3-5, 117-119, and 534-541. Applicants contend that these peptides are all closely related to the parent peptide DP-178 (SEQ ID NO.: 1). It is noted that SEQ ID NOS.: 1 and 3-5 are all directed toward full-length DP-178 peptides derived from different HIV-1 isolates (e.g., LAI, SF2, RF, and MN, respectively). The peptides corresponding to SEQ ID NOS.: 117-119 are directed toward amino-terminal truncations of the parent sequence (e.g., one, two, and three amino acids, respectively). Applicants assert that the truncated peptides "show no significant modification of the anti-viral activity" as compared to the parent DP-178 peptide. Finally, SEQ ID NOS.: 534-541 are directed toward peptidic variants having a single amino acid substitution. New claims were also introduced that are directed toward independent and distinct inventions (see paragraph 3 below).
- 2. As previously set forth, this application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. The regulations governing the claiming of different § 121 and 372. inventions in one national application are set forth under 37 C.F.R. § 1.141, 1.475, and 1.499. Applicants are reminded that if multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto, will be considered as the main invention in the claims (refer to PCT Article 17(3)(a) and \$1.476(c)). There appear to be three different products in the claimed invention as follows: (i) natural viral variants of the HIV-1 gp41 DP-178 (aa 638-673); (ii) amino-terminal truncations of DP-178; and (iii) variants of DP-178 containing single amino acid substitutions. Applicants are required to elect a single group of peptides (one of the peptide groups set forth in

- (i), (ii), or (iii)).1 Contrary to applicants' assertions, these peptides do not share a common special technical feature. While they are all derived from the same general region of HIV-1 gp41 (aa 638-673), nevertheless, they all contain unique amino acid sequences and different biological and physicochemical properties. For instance, the truncated peptides all show a reduction in T21 binding activity (see Table 2 of Lawless et al., 1996, Biochemistry 35:13697-13708). The same table also illustrates that single amino acid substitutions also affect the peptide activity in an unpredictable manner. Thus, the skilled artisan cannot reasonably predict how any given truncation or substitution will effect the various activities of the peptides of interest. Claims 1, 3, 4, 6, 19-21, 31, and 36-39, appear to be directed toward these peptides. Claims 52-58 also appear to be directed toward said peptides. However, the response and the claims fail to provide appropriate sequence identifiers for each of the peptides claimed. Applicants are required to provide appropriate SEQ ID NOS .: for these sequences and indicate which group, if any, they fall into. The Examiner would also consider a single method of using the elected peptides as set forth in claims 44-47.
- 3. This application also includes a number of other groups which do not share a special technical feature with the aforementioned group. Claims 32-35, 40-43, and 48-51 directed toward various DP-178 peptides as mentioned supra that have been conjugated to a blood component and method of use. These peptides share a different chemical structure (conjugated v. unconjugated) which will impart different functional activities upon each group of peptides.
- 4. Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, applicants are required to complete the response within a time limit of one month, or thirty days, whichever is the longer, from the mailing date of this letter. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 C.F.R. § 1.136(a) OR (b).
- 5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, or (703) 308-4315. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.
- 6. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The

The Examiner would consider reviewing a reasonable number of peptides (up to a maximum of ten) from each group. If the peptides of group (i) are elected, the Examiner would consider DP-178 sequences from up to ten different isolates. If the peptides of group (ii) are elected, the Examiner would consider at total of ten different amino-truncations. Finally, if the peptides of group (iii) are elected, the Examiner would consider a total of ten single amino acid variants.

examiner can normally be reached Monday through Thursday from 9:00 AM to 7:00 PM (Eastern Standard Time). A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner are unsuccessful, the Examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist at (703) 308-1235.

Respectfully,

Jeffrey S. Parkin, Ph.D.

Patent Examiner . Art Unit 1648

15 May, 2003